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10/582,445	09/25/2006	Yu Sing Hooi	18202.0002U1	7585
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Ballard Spahr LLP			REICHL, KARIN M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/582,445

**Applicant(s)**

HOOI, YU SING

**Examiner**

Karin M. Reichle

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 19-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19-23 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The response is considered to be the response of 2-12-09 except for the amendments to the specification and the response filed 10-9-09.

### ***Information Disclosure Statement***

1a. The information disclosure statement filed 10-9-09, contrary to Applicant's remarks, was not filed prior to the first Office action on the merits. It is noted however that payment of the fee set forth in 37 CFR 1.17(p) was authorized. Therefore it was not only placed in the application file, but the information referred to therein considered.

### ***Specification***

#### ***Drawings***

2. The drawings were received on 2-09. These drawings are not approved. Not only does the new Figure 5 not show a portion of the pad and sheath as described, e.g. see the terminal ends of all the layers, e.g. 4a and 4b, which do not show they are part of a section, but the added page is not properly numbered, e.g., 1/3, nor are the originally filed pages renumbered to reflect the addition of a Figure. Therefore see the following paragraph.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sheath opening through the pad, the pad layers, the sheath tube layers as claimed in claims 1-15 and 19-

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23 and 25 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because a Figure 5 as set forth on page 11 should be provided. Also the layers and tubes should be shown and denoted as set forth on pages 13-14 as now amended. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as

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“amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Description*

5. The abstract of the disclosure is still objected to because terminology which can be inferred, i.e. “is disclosed”, and legal terminology, i.e. “comprises”, should be avoided. Correction is required. See MPEP § 608.01(b).

6. The disclosure is objected to because of the following informalities: 1) See paragraph 4 *supra*. The description of the invention should be consistent with the Figures. 2) Claim 1, and thereby the claims that depend therefrom, now require a sheath that is resiliently expandable in a radial direction but not in a longitudinal direction. Page 7, lines 16-24 relied upon by Applicant for such amendments sets forth:

Nonetheless, the sheath should be able to receive a finger, which is likely to have roughly the same or a slightly larger diameter than a small conventional tampon. It is therefore particularly preferred that the sheath is resiliently expandable in a **radial direction** to receive a finger during insertion of the product into the vagina. **For example**, the sheath may be

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elastic in (only) a circumferential direction. (Significant elasticity in a longitudinal direction may be undesirable as it can lead to misplacement of the plug). **More specifically**, the absorbent and liquid impermeable tubes may be elastic in a circumferential direction. (Emphasis added).

Therefore, at the very least, see also the discussion *infra* in paragraphs 7 and 9, the claims and such page 7, lines 16-24 relied upon for support of the amendments are not consistent since it is not described that there is expandability in the radial direction but not in the longitudinal direction but rather that there is elasticity only in the circumferential direction but not in the longitudinal direction. Such page 7, lines 16-24 is inconsistent with itself too since, e.g., the circumferential direction is not an example of a radial direction. Note page 14, last paragraph as originally filed also. A consistent description of the invention throughout the entire application should be set forth.

Appropriate correction is required.

7. The amendment filed 10-09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendments to page 4, line 13 and page 7, line 16.

Applicant is required to cancel the new matter in the reply to this Office Action.

With regard to the amendments to page 4, line 13, see the discussion in claim 6 *supra* of section 2) and the discussion in paragraph 9 *infra*, and with regard to the amendments to page 7, line 16, note the original description, i.e. "Nonetheless, the sheath should be able to receive a finger, which is likely to have roughly the same or a slightly larger diameter than a small conventional tampon. It is therefore particularly preferred

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that...", i.e. the original description set forth, as best understood, see paragraph 6 *supra*, that the expandability in a certain direction was a particular preference, not a requirement as now set forth due to the amendments. Also note MPEP 2163.05, I. Therefore, as best understood and at the very most, while the original description set forth a particular preference for a sheath which is elastic only in a particular direction to enable receipt of the finger, this is not what is now described by such amendments. If Applicant maintains such amendments, the portion of the original specification which provides support therefor should be set forth.

#### ***Claim Objections***

8. Claims 9, 11 and 25 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Note that if the sheath is resiliently expandable as claimed in claim 1, such is flexible as claimed in claim 9 and that the joining of claim 1, see esp. lines -23 of claim 1, is not further limited in claim 25, note paragraph 11 also.

#### ***Claim Rejections - 35 USC § 112***

9. Claims 1-15, 19-23, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 now requires a sanitary product for insertion into a human vagina, the product comprising an internally wearable absorbent plug and an externally wearable absorbent pad joined to one another by a sheath that opens through the pad and is resiliently expandable in a radial direction, but not in a longitudinal direction, such that a wearer's finger can be received in the sheath to assist insertion. Applicant relies upon page 7, lines 16-24 as filed. See discussion in paragraphs 6-7 supra. Therefore, as best understood and at the very most, while the original description set forth a sheath which is elastic only in the circumferential direction but not the longitudinal direction to enable receipt of the finger, this is not what is now claimed. If Applicant maintains such claim language, the portion of the originally filed application which provides commensurate scope for the combination of each claim in a single embodiment should be set forth.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a



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nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-15, 19-23 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 11/920481. Although the conflicting claims are not identical, they are not patentably distinct from each other. Since there was no administrative delay, the one way *In re Vogel* test applies, i.e. are the claims of the instant application obvious in view of the other application claims? The answer is yes. Claim 1 of the instant application is broader with regard to some aspects and narrower with regard to other aspects of the claims of the other application. With regard to the broader aspects (e.g. the instant application does not require a line of weakness, see claim 1 in the other application), once an applicant has received a patent for a species or more specific embodiment, he is not entitled to a patent for the generic or broader invention. This is because the more specific anticipates the broader, i.e. the patented claim anticipates the application claim. See *In re Goodman*, supra. With regard to the narrower aspects (e.g. the instant application claim 1 requires a sheath which is resiliently expandable in a radial direction to be capable of receiving a finger, but not in a longitudinal direction), note claims, e.g., 18 and 17 in the other application as originally filed and as now amended), To make a sheath as claimed in the other application, e.g., claim 18, which is capable of receiving a finger also resiliently expandable in a radial direction as claimed in claim 17 of the other application would be obvious to one of ordinary skill in the art in view of the

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recognition that such provides the sheath with the capability of receiving a finger as desired.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Language Interpretation*

12. The claim terminology is interpreted in light of the definitions on page 4, line 25-page 5, line 1 (It is noted that such does not require wearing entirely inside or outside) and page 8, lines 18-20. Any other claim language not specifically defined has been interpreted in view of the usual and common meaning of such, e.g. the dictionary definition. Claim 25 is still considered a claim depending from claim 1 and thereby a product by process claim, see MPEP 2113. With regard to the claims, see the discussion in paragraphs 7 and 9 *supra* and MPEP 2163.06, I.

### *Response to Arguments*

13. Applicant's remarks have been carefully considered but are deemed either moot in that the issue discussed has not been reraised or not persuasive for the reasons discussed *supra*.

### *Conclusion*

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any new grounds of rejection were necessitated by the amendments to claim 1. Note also paragraphs 1a and 10-11 and MPEP 609.04(b), II.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Karin M. Reichle/  
Primary Examiner, Art Unit 3761

January 21, 2010